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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,040	02/20/2002	Peter L. Ryan	RU-0176	6411

7590 01/13/2005

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EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,040	RYAN ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10-27-04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the Office Action mailed on July 28, 2004 has been acknowledged. Currently, claim 1 is pending and has been amended.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is drawn to a method for evaluating treatment efficacy in pregnant mares affected by a disease or condition that alters placental function and results in a problematic pregnancy or delivery. Claim 1 further measures a first level of relaxin in plasma of a pregnant mare that has or is suspected of having a disease or condition that alters placental function, wherein the level is measured before administration of

drug or treatment for the disease or condition. Claim 1 further measures levels of relaxin in plasma of the mare following administration of the drug or treatment from the first day of treatment until time of delivery in the mare, wherein a failure of the plasma relaxin levels to increase following drug or treatment administration is indicative of a non-effective treatment in preventing a problematic pregnancy or delivery in the mare.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al (one) (Breed Differences in circulating Equine Relaxin, Biology of Reproduction, 1992, Vol. 46, pages 648-652) in view of Stewart et al (two) (Relaxin activity in foaling mares, Journal of Reproduction and Fertility. Supplement, (1982) Vol. 32, pages 603-609)

Stewart et al (one) teaches a method for measuring levels of relaxin in plasma of a pregnant mare before and after the administration of a drug or treatment (see abstract and introduction) wherein a homologous equine relaxin Radio Immunoassay (RIA) has been developed and used to measure plasma relaxin activity in thoroughbred mares during gestation until the time of foaling. Burros and Thoroughbred mares stimulated to deliver with oxytocin (treatment) showed an elevation in relaxin levels wherein the sensitivity to oxytocin (treatment) appears to develop late in gestation, as mares induced to abort in midpregnancy did not show a rise in relaxin (page 651, column 2, paragraph 2). Animals that exhibited adverse pregnancy outcomes had depressed relaxin concentrations at some point during gestation prior to the loss (page 651, column 2, paragraph 2).

Stewart et al (1) does not teach the evaluation of a treatment wherein the failure of the plasma relaxin levels to increase following a treatment or drug is indicative of a non-effective treatment in preventing problematic pregnancy or delivery in the mare. Stewart et al measures relaxin levels in ***blood*** as well as plasma (page 651, column 1, paragraph 3).

However, Stewart et al (two) teaches the administration of oxytocin in pregnant mares resulted in an increase of plasma relaxin levels at foaling and after foaling, but when oxytocin was administered to mares after placental delivery, the mares failed to elicit an increase in relaxin levels.

It would have been obvious to one of ordinary skill in the art to modify the teaching of Stewart et al (one) to include evaluating oxytocin as a treatment for conditions that alter placental function because increase and decrease in relaxin levels are directly correlated with placental function as disclosed in Stewart et al (two). One of ordinary skill in the art would have been motivated to use oxytocin on mares with a disease or condition to determine if levels of relaxin can be stabilized in mares with a disease or condition that would alter placental function.

Response to Arguments

4. Applicant argues that claim 1 has been amended to indicate that administering the drug or treatment to the mare to improve pregnancy outcome. Applicant argues oxytocin is not established in the art as a drug used for treatment of a disease or condition that alters placental function so that a problematic pregnancy or delivery in a

mare is prevented. Applicant asserts that oxytocin is recognized in the art of equine reproduction as used to treat mares for flushing uterine fluid, for induction of parturition, and for retained placenta. This argument is noted but not found to be persuasive.

In response, although applicant asserts that oxytocin is not recognized in the art as a drug used for treatment is noted, however, applicant has recited that oxytocin is used for a mare that has a retained placenta. In the examiner's view, it appears that a retained placenta constitutes altered placental function and therefore oxytocin would be administered to release the placenta. Further, it has not been established or taught by the instant claim 1 that the administration of a drug or treatment to a mare has or will improve pregnancy outcome, the claims has only taught the evaluation of such a drug.

5. Applicant argues that it would not be obvious to one of skill in the art that a positive correlation exists between improved pregnancy outcome upon treatment of a disease or condition and an increase in circulating relaxin levels. This argument is noted, but not found to be persuasive.

In response, it is the position of the examiner's that one of ordinary skill in the at would evaluate oxytocin as a treatment for conditions that alter placental function (retained placenta) because an increase and decrease in relaxin levels are directly correlated with placental function as disclosed in Stewart et al (two). Further, it also would be expected that it would improve pregnancy outcome, which includes the health of the mare, to treat for retained placenta.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 5711-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis
Remsen Bldg.
Room 3D58
January 5, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER